

REMARKS

In the office action dated September 9, 2005, claims 1-21 were pending. Claims 8, 18 and 19 were indicated as allowable but objected to for depending from a rejected base claims. Claims 1-7, 9-17, 20 and 21 stand rejected. Claim 8 has been amended in this response to correct a typographical error, and has not been narrowed or amended for any reason related to patentability. Claim 10 has been amended to clarify the direction from which the cutting instrument is advanced. Reconsideration of the present application as amended and including claims 1-21 in view of the remarks that follow is respectfully requested.

Claims 1-4, 6-7 and 9 were rejected as being anticipated by U.S. Patent No. 5,700,264 to Zucherman et al. Zucherman et al. discloses an instrument set 20 that includes an alignment probe 22, a cylindrical spacer 62, and a cutter 34. Zucherman et al. discloses that the alignment probe 22 is inserted first into the disc space and then rotated to anchor head end 24 to the adjacent vertebrae. Spacer 62 includes a central bore 64 and "is placed over the post 26 as shown in Fig. 8." Col. 4, line 36-37. Cutter 34 is then advanced over the spacer 62 until it contacts head end 24. When this is accomplished, the alignment probe is rotated to disengage the vertebra, and "the entire instrument set including the alignment probe 22 and the cutter 34 can be removed with the bone and disk tissue captured therebetween." Col. 4, lines 61-64.

Bore 64 is oriented to extend between and open at the leading and trailing ends of spacer 62. Spacer 62 has a solid body extending from the longitudinal bore 64 to the respective upper and lower surfaces, as plainly shown by the section view of spacer 62 in Figure 8. Furthermore, Zucherman et al. discloses that bore 64 receives the elongate post of the alignment probe 22. The office action asserts "cavity" 64 is capable of receive cut material. However, there is no disclosure of any such capability in Zucherman et al., nor is it clear how advancing cutter 34 distally along spacer 62 could deposit bone material in bore 64 since bore 64 extends and opens in the same directions in which cutter 34 is moved, and during such movement bore 64 is occupied post 26. Accordingly, it would not appear to be possible to deposit bone material in bore 64 since it is occupied by post 26 whenever spacer 62 is positioned between vertebrae.

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In contrast, claim 1 is directed to a method for preparing a spinal disc space and recites: "inserting a body portion of a distractor into the spinal disc space with an upper surface of the body portion adjacent an endplate of an upper vertebra and a lower surface of the body portion adjacent an endplate of a lower vertebra; advancing a cutting instrument over the body portion to remove material between at least one of the upper and lower surfaces of the body portion and the adjacent vertebra; and depositing cut material into a cavity formed in the body portion, the cavity opening toward at least one of the upper and lower surfaces." Since Zucherman et al. fails to disclose these method step limitations recited in claim 1, it cannot anticipate claim 1 and withdrawal of this basis of the rejection is respectfully requested.

Furthermore, claims 2-4, 6-7 and 9 depend directly or indirectly from claim 1 and distinguish Zucherman et al. at least for the reasons claim 1 distinguishes Zucherman et al. Accordingly, withdrawal of this basis of the rejection of claims 2-4, 6-7 and 9 is respectfully requested.

Claims 16-17 and 20-21 were rejected as being anticipated by U.S. Patent No. 5,722,977 to Wilhelmy. The office action asserts that Wilhelmy discloses a method that includes "inserting a body portion of a distractor, 15, into the spinal disc space, advancing a cutting instrument, 7, over the body portion into the spinal disc space, and limiting advancement of the cutting instrument into the spinal disc space by contacting the cutting instrument with a distal end wall of the body portion." A review of Wilhelmy does not reveal any such disclosure. Rather, Wilhelmy discloses limiting advancement of the cutting instrument by contacting the cutting instrument with a proximal end wall of a body portion of the distractor. At col. 8, lines 5-12, Wilhelmy discloses that the rear wall 44 of the osteotome head 36 "comes into abutting relationship with the surface 27 of the posterior base 16" which is clearly a proximal end wall of the body portion of the distractor, as shown in Fig. 18.

In contrast, claim 16 recites a method for preparing a spinal disc space that includes: "inserting a body portion of a distractor into the spinal disc space; advancing a cutting instrument over the body portion into the spinal disc space; and limiting advancement of the cutting instrument into the spinal disc space by contacting the cutting

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instrument with a distal end wall of the body portion." As demonstrated above, there is no disclosure of the method recited in claim 16 by Wilhelmy, and withdrawal of this basis of the rejection of claim 16 is respectfully requested.

The office action also asserts that Wilhelmy discloses a distractor 15 that a body with a distal end wall that "includes a first width" and a cutting instrument 7 with a "distal cutting end including a second width that is less than the first width". The office action provides no indication of where Wilhelmy discloses that the distal cutting end of the cutting instrument 7 has a width that is less than the width of the distal end of distractor 15. In direct contrast, Wilhelmy discloses an arrangement where the distal end wall of the distractor body has a width that is less than the width of the distal cutting end of cutting instrument 7. This is clearly illustrated in Figures 15-20 where the cutting instrument is advanced over the distractor and the distractor is encapsulated by the cutting instrument on all sides.

Claim 17, which depends from claim 16, recites: "wherein: the distal end wall includes a first width; and the cutting instrument includes an elongated shaft having a distal cutting end, the distal cutting end of the shaft configured to interfit with the body portion and includes a distally opening channel to receive the body portion of the distractor, the distal cutting end including a second width that is less than the first width." Accordingly, withdrawal of this basis of the rejection of claims 17 and 20-21 depending from claim 16 is respectfully requested.

Claims 10-15 were rejected as being anticipated by U.S. Patent No. 5,423,825 to Levine. Claim 10 has been amended and is directed to a method for facilitating preparation of a disc space between adjacent vertebrae and recites: "providing a distractor insertable into the disc space, the distractor including a body portion extending between a leading end and a trailing end, the distractor further including at least one flange extending from the leading end towards the trailing end of the body portion, the at least one flange forming a slot along the body portion; and providing a cutting instrument advanceable over the body portion from the trailing end into the slot formed between the body portion and the at least one flange of the distractor."

Assuming *arguendo* that Levine discloses a distractor, it includes a flange 53

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forming a slot 21 that opens at the leading of the body 19 to receive blade 45. Levine requires the open end of the slot to be oriented toward the leading end of body 19 so that the cutting edge of blade 45 is oriented distally when blade 45 is secured in slot 21. The proximal end of slot 21 toward the trailing end of the body is closed and recessed into body 19. Blade 45 therefore cannot be advanced over body 19 from the trailing end of body 19 into slot 21. Rather, blade 45 must be advanced into the slot from the leading end of body 19. Therefore, Levine cannot anticipate claim 10, and withdrawal of this basis of the rejection is respectfully requested.

Furthermore, claims 11-15 depend directly or indirectly from claim 10 distinguish Levine at least for the reasons claim 10 distinguishes Levine. Accordingly, withdrawal of this basis of the rejection of claims 11-15 is respectfully requested.

Claims 1-7 were rejected under 35 USC 103(a) as being unpatentable over Wilhelmy in view of U.S. Patent No. 6,641,582 to Hanson et al. Applicants reserve the right to swear behind the filing date of Hanson et al. in this application or in any continuing application in order to remove it as a reference.

The office action admits that Wilhelmy does not disclose depositing cut material into a cavity formed in the body portion. It is respectfully submitted that Hanson et al. fails to supply any teaching or disclosure that addresses this deficiency in Wilhelmy. In Hanson et al. instrument 10 includes paddles 20, 21 defining a height  $P_H$  between edges 44a, 44b and edges 45a, 45b, respectively. These edges contact the vertebral endplates to provide distraction. Between the opposite edges 44a, 45a and opposite edges 44b, 45b, the instrument includes a cutting edge 23 that extends beyond the height dimension  $P_H$ . Openings 24 are thus formed in the portion of the instrument that forms cutting edge 23, and move along with the instrument as it is advanced into the disc space. Accordingly, the instrument in Hanson et al. requires simultaneously advancing the cutting portion and the distracting portion of the instrument between the vertebrae.

Wilhelmy, on the other hand, contemplates a procedure where the distractor is first inserted, and the cutter instrument is advanced over the inserted distractor. The distractor acts as a guide to precisely guide the penetration of the cutter instrument. If Wilhelmy were modified according to teachings of Hanson et al. then the cutting

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instrument would be provided with openings to deposit cut bone material in the space between the cutter and the distractor as the cutter is advanced over the distractor. However, there is still would be no teaching or suggestion of providing any cavity in the distractor. The method in claim 1 includes "inserting a body portion of a distractor into the spinal disc space with an upper surface of the body portion adjacent an endplate of an upper vertebra and a lower surface of the body portion adjacent an endplate of a lower vertebra; advancing a cutting instrument over the body portion to remove material between at least one of the upper and lower surfaces of the body portion and the adjacent vertebra; and depositing cut material into a cavity formed in the body portion, the cavity opening toward at least one of the upper and lower surfaces."

Claims 2-7 depending directly or indirectly from claim 1 distinguish the combination of Wilhelmy and Hanson et al. at least for the reasons provided above for claim 1 and for other reasons. For example, claim 5 recites "wherein advancing the cutting instrument includes contacting a distal end of the body portion to limit advancement of the cutting instrument into the disc space." As discussed above, Wilhelmy fails to disclose or suggest this feature, and Hanson et al. fails to provide the disclosure or suggestion missing from Wilhelmy. Accordingly, withdrawal of this basis of the rejection of claims 2-7 is respectfully requested.

Examination of the present application as amended and including claims 1-21 in view of this response is respectfully requested. The Examiner is encouraged to contact the undersigned by telephone to resolve any outstanding matters concerning the present application.

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